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Sarvpreet Singh[a], Shalin Shaunak[b], Sebastian C. K. Shaw[c]; John L. Anderson[c]; Vipul Mandalia[d]

[a] Department of Trauma and Orthopaedics, North West Anglia NHS Foundation Trust, Cambridgeshire, UK.

[b] Department of Trauma and Orthopaedic Surgery, East Sussex Healthcare NHS Trust, East Sussex, UK.

[c] Department of Medical Education, Brighton and Sussex Medical School, Brighton, East Sussex, UK.

[d] Exeter Knee Reconstruction Unit, Royal Devon and Exeter NHS Foundation Trust, Devon, UK.

Mr S Singh

Designation: Consultant Orthopaedic Surgeon

Email: Sarvpreet.Singh@nhs.net

Mr S Shaunak (corresponding author)

Designation: Specialty Registrar in Trauma and Orthopaedic Surgery, KSS Deanery

Email: shalin.shaunak@doctors.org.uk

Dr SCK Shaw

Designation: Honorary Research Fellow

Email: Sebastian.shaw@doctors.org.uk

Mr JL Anderson

Designation: Principal Lecturer

Email: J.Anderson@bsms.ac.uk

Mr. V Mandalia

Designation: Consultant Orthopaedic Surgeon

Email: Vipulmandalia@nhs.net

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Abstract:

Background: Anterior cruciate ligament (ACL) injury is a common sports injury. Symptomatic knee instability after this injury is usually treated operatively through ACL reconstruction. The surgery involves a tendon graft being fixed in bony tunnels drilled through femur and tibia. The fixation of the graft is of critical importance to achieving good results. One of the commonest devices used to fix the graft in the femoral bony tunnel is a fixed loop cortical suspensory device. More recently, adjustable loop cortical suspension devices have been introduced, and have gained popularity for ACL reconstruction. These allow for adjusting the length of the suspension loop after insertion. There is currently much debate concerning whether the adjustable loop devices are superior or inferior to the fixed loop devices.

Purpose: To critique and review the current biomechanical and clinical evidence on the use of adjustable loop devices in hamstring ACL reconstruction. To our knowledge, there have been no previous reviews of this topic.

Study Design: Systematic review.

Methods: This systematic review was conducted in accordance with PRISMA. Five databases were searched using multiple search terms, and MeSH terms where possible. The following limits were applied: papers published in English; and papers published in the last twenty-one years.

Results: Eleven laboratory and six clinical studies were reviewed. The laboratory based studies have frequently shown elongation of adjustable loop devices to more than 3 mm under loading protocols, whereas the clinical studies have not shown any significant differences between the patients with fixed loop and the ones with adjustable loop devices.

Clinical significance: This review shows a discrepancy between laboratory based and clinical studies. The review of clinical studies in our paper would give future researchers confidence and act as a prompt to construct randomised clinical trials to investigate these devices further.

Conclusion: We feel more robust clinical randomised studies and trials are needed to evaluate these new devices.

Key Terms: Anterior cruciate ligament; Adjustable loop femoral cortical suspensory devices; Fixed loop femoral cortical suspensory devices; ACL reconstruction; Rehabilitation.

What is known: There are concerns about elongation of adjustable loops under increasing loads with cyclical loading.

What this study adds: The elongation in laboratory studies has not translated into symptomatic instability in clinical studies reported so far.

Introduction

Anterior cruciate ligament (ACL) ruptures are major and common sports knee injuries[1]. The non-operative management of this injury is dedicated rehabilitation of the knee. Symptomatic instability is usually treated operatively by ACL reconstruction. This involves reconstructing the ACL with a ligament graft or ligament and bone graft – comprising the patients' own tendons or a cadaveric graft. These grafts are often hamstring autografts, bone-patellar tendon-bone grafts, or allografts, or, less commonly, quadriceps tendon, tendo-achillis and synthetic ligaments[2 3].

The aim is secure fixation to allow for satisfactory healing of these grafts to the bone without movement; and to minimise lengthening of the graft that could otherwise compromise the stability of the knee post-surgery[3 4].

A tendon graft heals to the tunnels with Sharpey fibres at around 8 to 12 weeks postoperatively[5 6 7 8]. Forces that can occur during the initial rehabilitation have been estimated in various studies[9 10 11 12 13 14 15]. With single-leg squat and sit-to-stand exercises, the forces resisted by the ACL have been estimated from 59 to 142 Newton (N) [5 9 14 15]. Isokinetic seated knee extensions and isometric seated knee extensions have generated 349N and 396N of resisting force in the ACL respectively[15]. Rising from kneeling and stair climbing load the ACL by approximately 111N and 146N respectively[11]. Whilst level ground walking causes ACL forces to 303N to 355N[11 16]. Forces of up to 445 N have been reported when walking down an incline[10 12]. Therefore, the ideal ACL femoral fixation device requires the strength to sustain these forces or higher; minimising the elongation of the graft-implant construct that can ultimately lead to graft laxity; and allow healing to the bone tunnel.

The most common femoral fixation techniques used are cortical suspension devices, interference screws and trans-fixation devices. Although a definite consensus has yet to be reached[17 18], a cortical suspensory device remains one of the safe and commonly used options worldwide. This is usually used for hamstring auto- and allografts.

ACL reconstruction using hamstring grafts is common but technically challenging, especially in the presence of suboptimal autografts, (thinner or shorter tendons or smaller femur size). This presents a dilemma as research has reported that grafts of under 7mm are more prone to failure[19 20 21].

With thin autografts, the surgeon has limited options to bulk the graft. A technique commonly used, is tripling (as opposed to the usual doubling) of the two harvested hamstring tendons. This invariably leads to shortening of the graft and compromises the graft fixation and healing either in femoral or tibial tunnel, depending on the amount of the graft in the tunnel. The option is augmentation of these grafts with synthetic ligaments, but these frequently lead to complications: consequently this practice is not universally followed[22].

The femoral cortical suspensory devices commonly used for fixation are fixed loop devices – i.e. drilling a fixed pre-determined length of the femoral tunnel to insert these devices[23 24 25 26 27]. This is sometimes not possible, therefore, to address these challenges, adjustable loop femoral cortical suspensory devices have been recently introduced. These allow intra-operative flexibility of how much graft is pulled into the femoral tunnel, depending on the lengths of the graft and the tibial tunnel[28].

This article aims to review studies of these devices and to draw conclusions on the current state of play regarding femoral cortical suspension with adjustable loop devices.

Methods

The following databases were searched in order to locate relevant research: AMED (Allied and Complementary Medicine Database); CINAHL (Cumulative Index for Nursing and Allied Health Literature); the Cochrane Central Register of Controlled Trials; EMBASE; and Medline. The grey literature was also searched, using MeSH terms, via the website www.opengrey.eu.

Searches were limited to English language, published between 1st January 1997 and 31st December 2018 inclusive. The search terms used were: Anterior cruciate ligament reconstruction, cortical suspens*, cortical button*, adjustable loop*, fixed loop*, TightRope*, ToggleLoc* or ZipLoop*, RIGIDLOOP* or RigidLoop Adjustable*, procinch, Ultrabutton, EndoButton*, GraftMax, RetroButton*, XO Button*, EZLok, G-Lok, and g lok. These were also used in appropriate combinations.

The search strategy was guided by the PICOS [11] principles as follows.

Population:

Patients undergoing ACL reconstruction, or any ACL adjustable loop devices, being tested on their own or compared to the fixed loop devices.

Intervention:

Clinical studies –ACL reconstruction surgery with adjustable femoral cortical loop devices.

Biomechanical studies – testing of loop devices on a rig, using porcine femur specimens or cadavers.

Comparison:

Clinical studies –patients who had ACL reconstruction with adjustable loop devices versus patient's with fixed loop ACL reconstruction or with the patient's normal knee.

Biomechanical studies –adjustable loops versus fixed loops after loading on mechanical rigs, in porcine femur specimens or implanted in cadavers.

Primary Outcome:

Clinical studies – 3mm or more anterior laxity or symptomatic instability of the reconstructed knee versus the normal knee of the patient, judged by clinical tests such as the Lachman and the Pivot-shift test or by KT-1000 arthrometer (MEDmetric Corp, San Diego, CA 92121).

Biomechanical studies – a lengthening of 3mm or more of the loop device after loading.

Secondary Outcomes:

In clinical studies these were Tegner Activity and Lysholm scores, and the SF -12 questionnaire. Some studies also mentioned bony tunnel widening due to loop devices. It was pull-to-failure of the loop device in the mechanical study.

Setting:

The settings for clinical studies were clinics; for the mechanical studies they were biomechanical laboratories or cadaveric workshops.

Question:

Do adjustable loop devices lengthen more than 3mm after simulated loading or cause symptomatic knee instability after the ACL reconstruction?

Inclusion criteria:

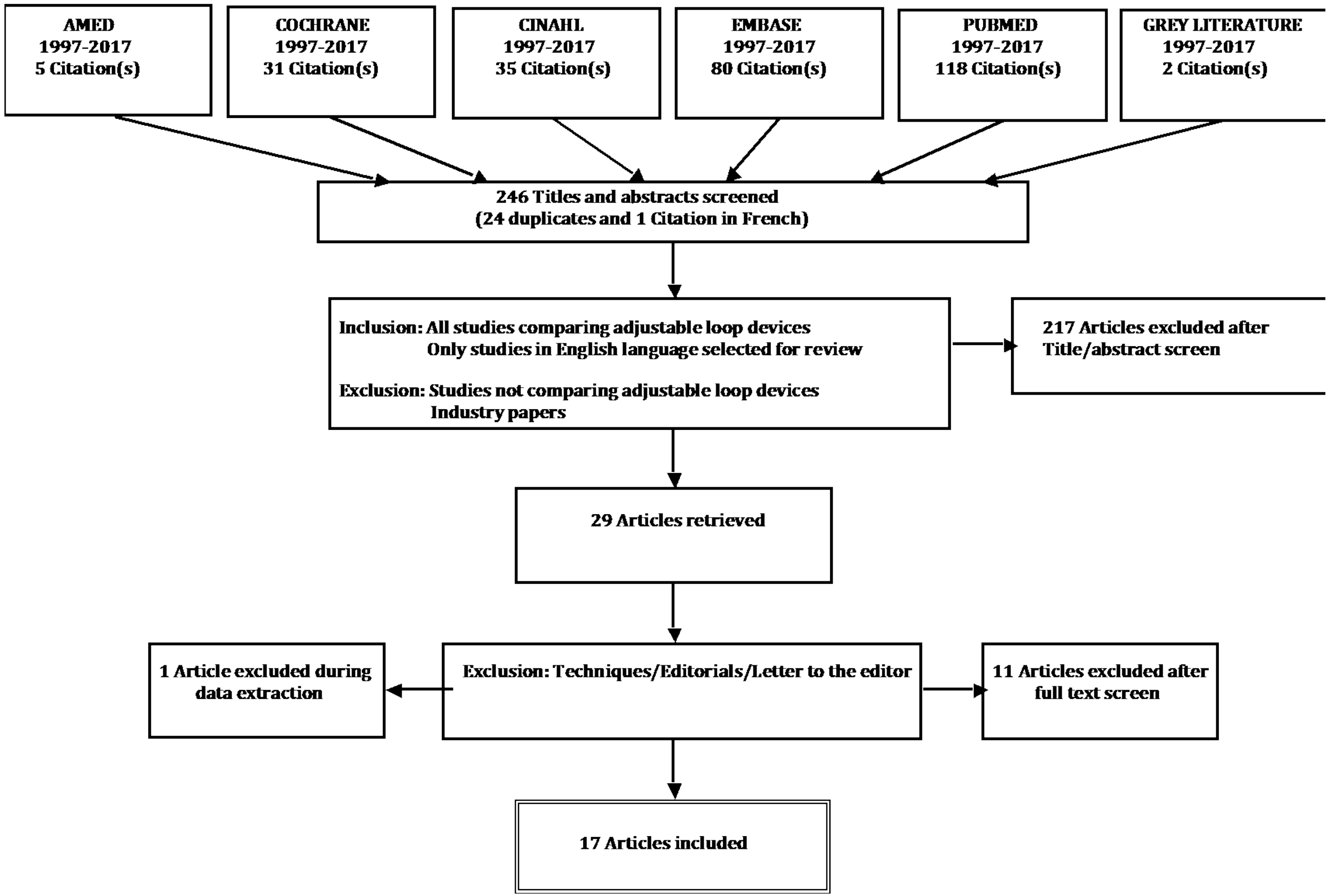
Inclusion criteria were: meta-analyses, systematic and literature reviews, randomised controlled trials (RCTs), cohort studies, case control studies, case series, case reports, cadaver and mechanical studies testing adjustable loops in comparison with fixed loops, with other adjustable loops, or in isolation.

Exclusion criteria:

Studies not including adjustable loop devices for ACL reconstruction or mechanical testing. Editorials, technique papers, industry papers and letters to the editor were also excluded.

Selection process:

Titles and abstracts were screened for relevance by the authors (SS, SSh, JLA and VM). If necessary, the complete article was reviewed to reach a decision. We also reviewed the references of papers in order to locate additional studies. See PRISMA flow chart in Figure 1.


AMED
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5 Citation(s)
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31 Citation(s)
CINAHL
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35 Citation(s)
EMBASE
1997-2017
80 Citation(s)
PUBMED
1997-2017
118 Citation(s)
GREY LITERATURE
1997-2017
2 Citation(s)
246 Titles and abstracts screened
(24 duplicates and 1 Citation in French)
Inclusion: All studies comparing adjustable loop devices
Only studies in English language selected for review
Exclusion: Studies not comparing adjustable loop devices
Industry papers
217 Articles excluded after
Title/abstract screen
29 Articles retrieved
Exclusion: Techniques/Editorials/Letter to the editor
1 Article excluded during
data extraction
11 Articles excluded after
full text screen
17 Articles included

Figure 1: Study flow diagram.

A standardized data extraction form was developed. The following data were extracted from the studies: type of study, numbers of samples, and testing protocols for biomechanical studies, numbers of patients, randomization, mean follow up gender, graft size, and outcome data (Table 1).

Table 1: Data extraction table - Study designs, testing protocols and conclusions

Study & year	***Study Type*** ***Biomechanical*** **or *clinical* or *review of literature***	***Sample size or patient number***	***Fixation devices – Fixed Loop (FL) versus Adjustable Loop (AL)***	***Loading protocol in mechanical studies and testing/scores in clinical studies***	***Testing set up in the laboratory* or *follow up clinics***	***Conclusions***
Conner[29] 2010	Biomechanical Porcine femur	8 samples of each type.	2 FL – EZLoc & EndoButton CL	The construct grafts were preloaded to 49N and cyclical loading was performed on MTS testing machine from	ACL reconstructions done with 8mm porcine extensor tendons in porcine femurs. 8 of each device were implanted	The Endo Button CL lengthened the least and showed higher failure loads than ToggleLoc with ZipLoop. The EZLoc samples did not survive the loading in sufficient numbers for statistical analysis. The fixation on

			1 AL – ToggleLoc with ZipLoop	50N to 450N for 2,000 cycles followed by pull to failure.	on the lateral femoral and on the anterior femoral cortex.	anterior cortex was stronger compared to the lateral cortex.
Petre[30] 2012	Biomechanical Device in a rig + Porcine femur	5 samples of each type for rig and 10 samples of each for porcine femur.	2 FL - XO Button & EndoButton CL 2 AL - ToggleLoc, ZipLoop & TightRope RT	Devices in the rig and the construct grafts were pre-loaded from 10 to 50N for 10 cycles, followed by 1000 cycles between 50 and 250N by an Instron machine. After cyclical loading for 1000 cycles the devices and the construct grafts were	Mechanical testing by setting up the device in a rig. ACL reconstructions done by 9mm bovine flexor tendon grafts in porcine femurs.	Device testing – Best to worst were EndoButton, TightRope RT, XO Button and ToggleLoc with ZipLoop. Construct testing - Best to worst XO Button, EndoButton CL, TightRope RT and ToggleLoc with ZipLoop, which crossed 3mm failure threshold for cyclic displacement.

				further displaced at 50mm/min until failure.		ToggleLoc with ZipLoop also lengthened the most before failure in both device only and construct testing. Overall, Fixed loop devices allowed less cyclic and initial displacement.
Barrow[31] 2013	Biomechanical Device in a rig.	6 samples each of each type were tested initially, then, 6 samples of ToggleLoc with ZipLoop & Tightrope RT were then	1 FL – 40mm EndoButton CL Ultra 2 AL – ToggleLoc with ZipLoop	Preconditioning between 10 and 50N for 10 cycles was done to remove the slack. Upon completion, construct displacement was recorded and reset to 0. Cyclic loading was	Mechanical testing by setting up the device in a rig. Adjustable loops were tested again after free suture end were tied in knots.	Both the adjustable loop devices lengthened more than 3mm after 4500 cycles. Tightrope RT reached clinical failure of 3 mm before ToggleLoc with ZipLoop. EndoButton CL Ultra did not reach clinical failure limit of 3mm with cyclic loading. TightRope RT also showed greater lengthening than ToggleLoc with Zip Loop, EndoButton

		tested after tying knots.	& TightRope RT	then performed between 10 and 50 N for 500 cycles by Instron machine. The force was increased in 25N increments every 500 cycles up to 250 n for a total of 4500 cycles. At completion of the cyclic loading protocol, each sample underwent load-to-failure testing at the rate of 20mm/min load to failure.		CL Ultra showed the least lengthening. TightRope RT. also showed lower loads to ultimate failure. Knotting improved the parameters of adjustable loop devices. Construct failure in both adjustable devices was near the button device, whereas the EndoButton CL Ultra was mid substance loop failure.

				Adjustable loops were also tested after free suture end were tied in knots.		
Firat[32] 2014	Clinical Retrospective case series.	Total of 78 patients from two surgeon series after autograft hamstring ACL reconstruction 46 with EndoButton CL vs. 32 with	I FL – EndoButton CL I AL - ToggleLoc with ZipLoop	Tests – Lachman, Pivot shift, KT-1000 arthrometer & active and passive joint range of motion. Scores - Tegner activity score, Lysholm, IKDC form.	Clinical testing at minimum of 2 years after operation.	No statistically significant differences in the parameters on clinical testing at 2 years by an investigator who was blinded to the type of loop used for ACL reconstruction. There was also no difference in the Tegner, Lysholm & IKDC scores. There was a statistical difference in femoral tunnel widening and the space above the graft in the femoral tunnel,

		ToggleLoc with ZipLoop		Imaging – Radiographs & MRI scans to look for femoral tunnel widening and space above the graft in femoral tunnel respectively.		both being less patients who had ToggleLoc with ZipLoop.
Eguchi[33] 2014	Biomechanical Device in a rig + Porcine femur	10 samples of each type tested in each subset so 20 in device and 20 in porcine femur.	1 FL – EndoButton CL 1 AL – TightRope RT	Devices in the rig and the construct grafts were pre-loaded from 50N for 3s till preload displacement reached a plateau. Then 50 to 250N for	Mechanical testing by setting up the device in a rig. ACL reconstructions done by 8mm bovine	In mechanical rig testing the displacement after preloading for the EndoButton CL was statistically lower than TightRope RT. The EndoButton CL also showed significantly higher ultimate tensile strength than the TR.

				2000cycles by MTS machine. After cyclical loading the loop devices were pulled to failure at 1mm/s. The bone tunnel length (kept constant at 35mm) and the study evaluated the loop displacement up to the preloaded state.	flexor tendon grafts in porcine femurs.	In contrast the construct graft testing did not show and statistical difference between the EndoButton CL and the TightRope RT groups.
Pasquali[34]	Biomechanical	6 samples of each type.	3 AL - ToggleLoc with ZipLoop,	Devices in the rig were preloaded from 5N to 67N for 10	Mechanical testing by setting up the device in a rig.	RigidLoop Adjustable performed better than TightRope RT, which performed better than ToggleLoc with ZipLoop for

2015	Device in a rig.		TightRope RT & RigidLoop Adjustable	cycles and then tested from 50N to 250N for 1000 by Instron machine. Load to failure conducted at a rate of 20mm/min.		lengthening under cyclical load. All the 3 loops lengthened less than 3 mm. For pull to failure the RigidLoop Adjustable and TightRope RT were stronger than TR ToggleLoc with ZipLoop ZL Study also described the locking mechanisms of the adjustable loop devices and their potential effects on the lengthening under cyclical loading.

Boyle[35] 2015	Clinical Retrospective case series.	Consecutive single surgeon series of 188 patients with autograft ACL reconstruction 115 with RetroButton vs. 73 with TightRope RT	1 FL – RetroButton 1 AL – TightRope RT	Tests – Lachman, Pivot shift, KT-1000 arthrometer from side-to-side. Graft failure - graft revision rates and timing.	Groups compared at six months, 1 year, 2-year post op.	No difference in side-to-side testing or graft failure rates between the two devices. They used 6mm anterior translation as sign of clinical failure rather than 3mm used most commonly in other studies.
Johnson[36] 2015	Biomechanical Device in a rig.	8 samples of each type tested, two additional groups of 8	3 FL – EndoButton, CL Ultra, RigidLoop & XO Button.	Devices in the rig were preloaded from 10N to 75N at for 10 cycles, followed by 1000 cycles of	Mechanical testing by setting up the device in a rig.	Lengthening was least for EndoButton CL Ultra followed by RigidLoop, then XO Button, then TightRope RT with re-tensioning, then TightRope RT without re-tensioning, then the ToggleLoc with

		devices each for adjustable loops tested with re-tensioning after pre-conditioning	2 AL – TightRope RT & ToggleLoc with ZipLoop	sinusoidal cyclic loading between 100-400N for 1000 cycles by an Instron machine. After cyclic loading the devices were then pulled to failure at 50 mm/min. The effect of re-tensioning after simulated preloading was evaluated for the 2 adjustable loop devices.	Adjustable loops tested again after knot tying + Re-tensioning	ZipLoop with re-tensioning, then TightRope with ZipLoop without re-tensioning. ToggleLoc with ZipLoop lengthened more than 3mm both with and without re-tensioning. All the other loop devices lengthened less than 3mm. All loops had adequate strength for pull to failure, the best being ToggleLoc with ZipLoop after re-tensioning.

						No diff in biomechanical properties of both adjustable loops after re-tensioning.
Noonan[37] 2016	Biomechanical Device in a rig + Porcine femur	5 samples of each type in tested in 3 phases.	1 FL – 1 FL – EndoButton CL 1 AL – TightRope RT	3 phases, each phase had subsets where the TightRope RT was either re-tensioned or tied in knot and both re-tensioned and tied in knot. This was to evaluate the effects of re-tensioning and	Mechanical testing by setting up the device in a rig. ACL reconstructions done by bovine extensor tendon grafts in porcine femurs.	Phase 1 - The TightRope RT demonstrated an increase in cyclic elongation compared to EndoButton CL but was unlikely to be of clinical significance. Phase 2 - The elongation was more and could be of clinical significance. These increased elongations were eliminated

				knot tying on the biomechanical properties of an adjustable loop device. Phase 1 - 50 to 250N for 4500 cycles Phase 2 - Unloaded cyclical loading 10 to 250N for 4500 cycles and Phase 3, - Construct tendon		by 88% after re-tensioning and knot tying. Phase 3 - The re-tensioning and knot tying of TightRope RT reduced fin the tendon construct reduced the final cyclic elongation by 50%.

				The cyclical loading was done by MTS machine.		
Lanzetti[38] 2016	Clinical Prospective trial.	Two groups of 22 patients each. Both had autograft hamstring ACL reconstruction. Group A having TightRope RT & Group B with EndoButton.	1 FL – EndoButton 1 AL – TightRope RT	Tests – Lachman, Pivot shift, KT-1000 arthrometer. Scores - Tegner activity score, Lysholm, & IKDC form. Imaging – CT scan to measure the width of	All patients assessed at 12 months by operator independent from the surgeon.	No statistically significant found in the laxity or the femoral tunnel enlargement. Transtbial technique was used for the ACL reconstruction.

		Selected patients had ACL graft size and femoral tunnel size 9mm. Exclusion criteria - previous knee surgery, multi-ligament surgery, marked rotatory		the femoral tunnel at four different levels.		

		instability or systemic or connective tissue disease.				
Basson[39] 2016	Clinical Prospective case series	46 patients in prospective continuous single-operator monocenter study	1 AL - ToggleLoc with ZipLoop	Tests – GNRB arthrometer laximetry tests. Scores – IKDC subjective and objective, SF – 36	Tests done at 12 months follow up.	Fixation by ToggleLoc with ZipLoop demonstrated good functional and laximetric results, comparable with those reported with other femoral fixation devices using hamstring tendon grafts. The ToggleLoc with ZipLoop in ACL reconstruction using an STG graft

				Imaging – CT scans for femoral tunnel widening.		resulted in a highly significant widening of the femoral tunnel. This enlargement close to the joint line was correlated to impaired clinical findings.
Born[40] 2016	Cadaveric	12 knees – 6 of each type in matched pairs	2 AL - RigidLoop Adjustable vs. 6 TightRope RT	Single bundle 8 mm ACL reconstruction performed in cadaver knees with bovine tendons after debridement of the native ACL. Cadaver knees tested for laxity with native ACL, then tested for	Laxity testing by KT 1000 Graft to button lengthening tested by three-dimensional CT scanning.	No significant differences between the two loop devices with regards to the laxity outcomes or loop lengthening as measured by the button-to-graft distance migration.

				KT 1000 laxity after reconstruction and imaged with CT. After 1,000 cycles of antero posterior loading by MTS machine, the knees again tested for laxity and CT imaged for graft to button distance		

Choi[41] 2016	Clinical Retrospective cohort	Single surgeon retrospective series. Hamstring autograft ACL reconstructions in a total of 117 patients, 67 patients with fixed loop and 50 patients with adjustable loop	1 FL – EndoButton CL 1 AL – TightRope RT	Tests – Lachman, Pivot shift by blinded fellow. KT-1000 arthrometer by blinded orthopaedic technician. Scores - Tegner activity & Lysholm scores Imaging – Radiographs to measure the	Minimum of 2 years follow up.	The study found no difference in laxity and functional scores, and tunnel widening. However, the fixed-loop group showed better pivot-shift test. The surgeon used trans tibial technique for the ACL reconstruction.

				diameter of the femoral tunnel a 1-year.		
Wise[42] 2017	Clinical Retrospective case series.	Retrospective single surgeon case series looking at a total of 57 patients with 24 in the FL and group and 33 patients with AL.	2 FL – EndoButton & RetroButton 2AL – TightRope RT & ToggleLoc with ZipLoop	Tests – KT-1000 arthrometer. Scores - Tegner activity score, Lysholm & SF-12. Graft failure - graft revision rates.	KT-1000 analysis by blinded physical therapist Tegner, Lysholm and SF 12 form administered during clinic visit or online.	The study found no statistical difference in ACL graft laxity or postoperative functional outcomes between grafts fixed with adjustable or fixed loop technique.

Ahmad[43] 2018	Biomechanical	9 different devices tested with six samples of each device subjected to machine stressing	3 FL - (EndoButton CL Ultra, RetroButton & RigidLoop 6 AL - GraftMax Button, RigidLoop Adjustable TightRope RT	2000 cycle loading protocol at force increments between 50 and 500 N. Irreversible displacement (mm) and maximum load to failure was applied and measured in Nm.	Test: Servo-hydraulic mechanical testing machine (MTS) (MiniBionix 858, MTS, USA) for cyclic loading	Adjustable loop devices demonstrated both biomechanical inferiority and heterogeneity of fixation properties with three adjustable devices, however (RIGIDLOOP ™ Adjustable, Ultrabutton ◊, ProCinch™) demonstrating fixation capacities within the margins of clinical acceptance.

			UltraButton ToggleLoc ProCinch Six samples of each of the nine suspension			
Cheng[44] 2018	Biomechanical	3 devices subjected to both cyclic load and pull-to-failure conditions using a tensile	2 AL: GraftMax Button; TightRope RT	Cyclic load: 50–250 N for 1000 cycles Pull-to-failure conditions: 50 mm/h	Mechanical testing by setting up the device in a rig	EndoButton highest mean failure (1204.7 N) with GraftMax (914.2 N), knotted TightRope (868.1 N) and TightRope (800.1 N) Mean total displacement after 1000 cycles: Endobutton (0.76 mm),

		testing machine	1 FL: EndoButtonCL			GraftMax (2.11 mm), Tightrope (1.56 mm) and knotted TightRope 1.38 mm
Chang[45] 2018	Biomechanical	Adjustable-length loop and fixed-length loop devices: amount of displacement, temporal pattern of displacement, and ultimate failure load	1 FL: Endobutton Ultra 1 AL: Tightrope RT	Implants tested using 4,500 cycles of sinusoidal loading with high loads (100-400 N)	Device-only model (DOM) and a device–bone–soft-tissue graft construct model (CM).	DOM: adjustable-length loop device weaker (mean cumulative peak displacement of 1.91 adjustable-length loop device, 0.74 mm for the fixed-length loop device). Displacement of the adjustable-length loop device increased between 1,000 and 4,500 cycles; whereas fixed-length loop device reached a plateau. showed a weaker ultimate failure load (925 N vs 1,410 N)

						CM: No statistically significant difference in displacement of overall load to failure

Table 1: Data extraction.

Quality assessment process:

Three authors (SS, SSh and SCKS) conducted quality assessment of the studies independently before crosschecking for concordance using the Scottish Intercollegiate Guidelines Network (SIGN) criteria. Studies were scored according to these criteria. (Table 3)

Results

Seventeen studies were included. The quality assessment is shown in Table 3.

Study Quality	Studies
High +++ All or most criteria fulfilled	Barrow et al[31]; Johnson et al[36]; Noonan et al[37]
Moderate ++ Some criteria have fulfilled	Conner et al[29]; Petre et al[30]; Eguchi et al[33]; Pasquali et al[34]; Boyle et al[35]; Lanzetti et al[38]; Basson et al[39]; Born et al[40]; Choi et al[41]; Wise et al[42]; Ahmad et al[43]; Cheng et al[44]; Chang et al[45]
Low +	Firat et al[32]

Few or no criteria fulfilled	

Table 3: Quality assessment of studies

Of the eleven biomechanical studies, one used human cadavers[40]; six compared loop devices on a mechanical rig construct only[31 36 22 43 44 45]; one looked exclusively at porcine femur testing[29]; and three used both porcine and mechanical rig testing[33 37 30].

All biomechanical studies investigated elongation of loops under cyclical load and pull to failure, with some also testing elongation of adjustable loops after re-tensioning, knot tying[31] or both[36 37]. Most earlier investigators[31 33 37 34 30] except Conner et al[29] tested the loops with cyclical loads up to 250N. Conner et al (2010) and Johnson et al[36] (2015) tested loop devices to higher loads of 450N and 400N respectively. Three biomechanical studies tested loads for 1000 cycles. Two tested for 2000 cycles. Barrow et al[31] and Noonan et al[37] were the only ones to test loads over high number of (n= 4,500) cycles. Four clinical studies[35 41 32 42] were retrospective case series or cohort studies. One was a prospective cohort study following patients over twelve-months[38] whereas the other[39] was a prospective single operator case series with a mean follow up of thirteen-months.

Conner et al[29] were one of the earlier investigators in comparing the fixed loops EndoButton CL and EZLoc versus the adjustable loop ToggleLoc with ZipLoop. Although their main aim was to compare fixation on the lateral cortex versus the anterior cortex of porcine femur, they found that in the anterior cortex group, the ToggleLoc with ZipLoop exhibited higher 2000 cycle elongation (5.46 +/- 1mm) than EndoButton CL

(3.55 +/- 0.6 mm) ($p = 0.005$). The lateral cortex group could not be tested statistically, as an insufficient number of devices survived due to implant breakage during loading.

Petre et al's[30] mechanical rig and porcine femur model tested loops to 1000 cycles with up to 250 N of loading, and found the ToggleLoc with ZipLoop exceeded 3 mm displacement threshold (3.34mm). They concluded fixed loop devices demonstrated less cyclic displacement and that most displacement in adjustable loops occurred during the first cycle from preload to cyclic testing. (Petre et al., 2013b) (Petre et al., 2013b) (Petre et al., 2013b)

Barrow et al[31] reported that more cycles are needed to replicate the forces in ACL grafts post reconstruction as an average ambulatory person has greater than 6000 gait cycles in a day. They tested one fixed loop device against two adjustable devices with a high number of cycles (n=4500) on a biomechanical construct. They found that, although the ultimate tensile strength of all loops was satisfactory, both adjustable loop devices experienced clinically significant lengthening. Total displacement after 4,500 cycles of tensioning at variable loads was 42.45 +/- 7.01 mm for TightRope RT and 5.76 +/- 0.35 mm for ToggleLoc with ZipLoop. The TightRope RT reached clinical failure of 3 mm lengthening after fewer cycles (1349 +/- 316) than ToggleLoc with ZipLoop (2576 +/- 73) ($p<0.001$). They also noted that TightRope RT displayed the most significant decrease in lengthening after knot tying[10]. The lengthening after 4,500 cycles decreased from 42.45 +/- 7.01 mm to 13.36 +/-1.86 mm. Like Noonan et al[37] they found that lengthening was more prone to occur under relatively lower loads of around 10N.

Subsequent laboratory studies tested additional parameters of fixed and adjustable loop devices. Eguchi et al[33] tested, the TightRope RT adjustable loop and, the EndoButton fixed loop, keeping tunnel length in porcine femur constructs constant at 35mm. They found the TightRope RT lengthened more that 3mm in both isolated rig testing (4.05 mm) and in the porcine model (6.39 to 7.74 mm) P values . This improved on re-tensioning after preloading to less than 3mm. They also found that the TightRope RT loop lengthened more under cyclical loading between 1000 and 2000 cycles.

Pasquali et al's[34] study of three adjustable loop devices found that all lengthened less than 3mm. RigidLoop Adjustable performed best in their study with average displacement of 0.88 +/- 0.14 mm; followed by TightRope RT at 1.13 +/- 0.15 mm; then ToggleLoc with ZipLoop 2.12 +/- 0.16 mm. The RigidLoop Adjustable also had the highest average strength of the three loop devices tested P values. They made important observations on the mechanism of adjustable loop devices and divided these mechanisms into two categories: ToggleLoc with ZipLoop technology and TightRope RT rely on a "finger-trap" mechanism where one end of the suture end is spliced through the centre of the other suture end; whilst the RigidLoop Adjustable used a "sliding knot" mechanism.

Johnson et al[37] argued that forces experienced by the ACL graft in the initial rehabilitation period exceed the 250N tested by the earlier studies. They tested loops to 400N for 1000 cycles. They tested three fixed loop against two adjustable loops. The adjustable loop lengths were standardised to the fixed loop length of 20mm before testing. They found that adjustable loops lengthened more than fixed loops and one adjustable loop device tested (ToggleLoc with ZipLoop) lengthened more than 3 mm - with and without re-tensioning. The least amount of lengthening was observed for the

EndoButton CL Ultra (1.05 +/- 0.05 mm), followed by the RigidLoop (1.09 +/-0.16 mm), XO Button (1.65 +/- 0.43 mm), TightRope RT with re-tensioning (1.18 +/- 0.51 mm), TightRope RT without re-tensioning (2.20 +/- 0.62 mm), ToggleLoc with ZipLoop with re-tensioning (3.22 +/- 1.41 mm), and ToggleLoc without re-tensioning (3.69 +/- 2.39 mm). Like Eguchi[33] et al they noted that the biomechanical properties of adjustable loop devices improved after re-tensioning; but this improvement was insignificant.

Noonan et al[37] compared, the TightRope RT adjustable loop with, the EndoButton CL fixed loop. They aimed to demonstrate the effect of re-tensioning and knot tying on the adjustable loop device. Their protocol was similar to Barrow et al[31], i.e. higher number of cycles and loads stating from 10N. Like earlier investigators[31 33 37 34 30], they found the adjustable loop lengthened more than the fixed loop with cyclical loading; lengthening of the adjustable loop device in their study was not significant except at lower loads - similar to Barrow et al's[31] finding. The potential unlocking of "finger trap" type of mechanism possibly caused this due to loss of loop tension at lower loads. They also noted that adjustable loop devices lengthening at lower loads could be a clinical concern as the ACL experiences minimum loads approaching 0 N in mid-flexion[46 31 37 47]. Unlike Johnson et al[36], they found that re-tensioning and knotting improved the properties of the adjustable loops significantly. They noted that knotting was more effective than re-tensioning, but the combination of re-tensioning and knot tying produced better results than either in isolation. In the biomechanical construct, re-tensioning and knot tying reduced final adjustable loop device lengthening by 60 % (0.38 vs. 0.96 mm, $p = 0.00004$) when the cyclical loading was from 50 N to 250 N and by 88 % (0.51 vs. 4.22mm, $p = 0.014$) when the cyclical loading was done from 10 N to 250 N. They achieved similar results for their tendon/bone/implant model. After re-tensioning and knot tying the final lengthening of the adjustable loop device was reduced by 45 % (1.5 vs. 2.7 mm, $p = 0.001$).

Born et al.[40] in their human cadaveric study, compared two adjustable loop devices in 6 matched pairs of knees. The two sets of knees were tested for mechanical laxity at various knee flexion angles and button-to-graft distance migration. The results were measured after loading the knees in antero-posterior direction for 1,000 cycles with approximately 133.5N. They found no significant difference between the two groups in laxity and the button-to-graft distance (proxy for loop lengthening). They found the lengthening in RigidLoop Adjustable group was 0.61 +/- 0.6 mm and that in TightRope RT group was 0.53 +/- 0.6 mm ($p = 0.773$).

Ahmad et al.[43] focussed on the biomechanical testing of 9 different widely available devices. These were subjected to a 2000 cycle load with force increments between 50 and 500N. They demonstrated significant mechanical weakness in adjustable loop devices against fixed loop designs.

Cheng et al.[44] subjected three devices to both cyclic load and pull-to-failure via a rig. Their forces were a cyclic load between 50-250 N for 100 cycles and pull to failure of 50mm/hour respectively. On these grounds, the EndoButton had the highest mean failure (1204.7N) followed by the GraftMax (914.2N) and tightrope last (800.1N, up to 868.1N in a knotted setting). In terms of mean total displacement, this was not the same as above, with the EndoButton displacing 0.76mm after 100 cycles, the GraftMax 2.11mm and the tightrope displacing 1.56mm.

Chang et al.[45] compared adjustable-length loop and fixed-length loop devices in terms of amount of displacement, temporal pattern of displacement, and ultimate failure load. Implants were tested using 4,500 cycles of sinusoidal loading with high loads (100-400 N), in both a device-only model (DOM) and a device–bone–soft-tissue graft construct model (CM). In the DOM, they found that the adjustable-length loop device was weaker, with mean cumulative peak displacement of 1.91 mm for the adjustable-length loop device and 0.74 mm for the fixed-length loop device (P = .001). Displacement of the adjustable-length loop device was also incremental on cyclical loading, whereas the fixed-length loop device reached a plateau. In terms of the CM, no statistically significant difference in displacement of overall load to failure were found.

Of the six clinical studies, Firat et al[32] and Boyle et al[35] reported results of retrospective studies between patient groups. Lanzetti et al[38] reported a prospective non-randomised cohort study. Basson et al[39] conducted a study of 46 patients in a prospective single operator mono-centre study. They used ToggleLoc with ZipLoop. They looked at femoral tunnel widening and did GNRB arthrometer (Genorub, Rue du Chef Bataillon Henri Geret, 53000 Laval) laxity tests. They found ToggleLoc with ZipLoop fixation demonstrated good functional and laximetric results, comparable with other femoral fixation devices using hamstring tendon grafts. Choi et al[41,42] and Wise et al[42] were retrospective cohort studies. Choi et al[41] used trans-tibial technique for ACL reconstructions and in addition to ACL laxity at two years also looked at tibial and femoral tunnel widening. They found no difference in laxity or statistically significant tunnel widening comparing the adjustable loop cohort to the fixed loop cohort.

Wise et al's[42] single surgeon series used the fixed loop technique and then transitioned to using adjustable loops. A blinded assessor did KT-1000 testing; in addition they looked at the Lysholm and Tegner scores and Short Form Health Survey (SF-12). They found no significant difference between the two groups.

All the studies except Wise et al[42] used hamstring tendons for ACL reconstructions. Wise et al also used a variety of grafts, like tibialis anterior and bone-patellar tendon-bone graft. They also used allografts. Their use of different types of graft was distributed amongst both fixed loop and adjustable loop patients.

Firat et al[32] followed up patients of two surgeons - one using EndoButton CL, the other using ToggleLoc with ZipLoop. Both used antero-medial portals for femoral tunnel drilling. Patients were identified retrospectively and invited back for assessment. Assessors were blinded to the type of loop device used. They found no difference in parameters like Lachman and Pivot shift testing, KT 1000 reading difference on from side-to-side testing; or with Tegner activity level, Lysholm and International Knee Documentation Committee (IKDC) scores at 2 years.

Boyle et al[35] looked at the outcomes of KT-1000 readings, rates and timings of graft failures between their two groups up to 2 years of follow-up from surgery. One group had an adjustable loop device, the TightRope RT for ACL reconstruction; the other had a fixed loop device, RetroButton. The femoral tunnel was again antero-medial. There were no significant differences between the two groups in maximum side-to-side difference on KT 1000 testing up to 2 years post-operatively, or in graft failure rates between the two groups. They concluded that adjustable loop suspension does not loosen clinically after ACL reconstruction.

Lanzetti et al's[38] two prospective groups of patients were followed up for a year. Both groups had trans-tibial ACL reconstruction. Group A were treated with an adjustable loop device, TightRope RT. Group B had a fixed loop device, EndoButton CL. Their primary aim was to investigate widening of the femoral tunnel due to femoral cortical suspension fixation, but they also investigated laxity as a secondary measure. They assessed the laxity by Lachman test, Pivot shift test and KT 1000 testing They also did Lysholm and Tegner activity scores at 1 year and did not find any significant difference between the two groups.

None of these studies used randomization. None mention return to sports. Firat's[32] study does not mention size of graft. Lanzetti's[38] study and Basson's[39] study included only 9mm graft size for both groups; In Boyle's[35] study the adjustable loop group had a thicker graft (8.25 mm) than the fixed loop cohort (7.92 mm). This was statistically significant. Boyle's study[35] is unique in considering 5mm laxity as failure whereas other studies considered 3mm as the threshold of clinical failure. Their decision was informed by the International Knee Documentation Committee definition.

Discussion

Adjustable loop femoral cortical suspension devices are relatively new. They offer various advantages - chiefly, graft maximization in short femoral tunnels, avoiding multiple loop sizes in their inventory, avoiding over-drilling of the femoral tunnel, and obviating the need to calculate loop length. These devices also provide intra-operative flexibility in deciding how much graft length should be pulled into the femoral tunnel, depending on the graft length and the tibial tunnel length.

However, there have been recent concerns about the tendency of adjustable loop devices to lengthen in cyclical loading thus compromising effective graft length. This is critical especially in the first 8 to 12 weeks post-operatively, or the early phase of rehabilitation, when the graft healing takes place. Any lengthening at this stage would not only impair the tendon bone healing but also lead to functional knee instability. Almost universally the lengthening criterion for the failure of graft has been accepted as more than 3mm elongation or side-to-side difference[4].

Our review focussed exclusively on adjustable loop studies. We identified seventeen studies comparing properties of adjustable loops. Eleven were biomechanical laboratory studies[31 36 22 43 44 45 33 37 30 29 40]. Six were clinical studies[39 35 41 32 38 42].

All the biomechanical studies reported satisfactory pull to failure strengths for adjustable and fixed loops. Noonan et al reported the highest loads at failure under cyclical loading found in this review[37]. They reported a failure load of 786 +/- 166 N in their graft/femur construct for TightRope RT with cyclical loads of 50 to 250 N. This is still more than the loads of 150 to 590 N that have been estimated across the ACL in the early rehabilitation period[10 12 14].

Laboratory-based studies had individual strengths in the different loading protocols they tested; in addition, some tested the properties of adjustable loops after re-tensioning and/or knot tying[36 37]. One looked specifically at the locking mechanisms of adjustable loops[34]. It identified two main types of mechanisms; “finger trap” and sliding “knot-based” mechanisms in the loops. They noted that failure of “finger-trap” types, as seen in ToggleLoc with ZipLoop and TightRope RT may occur from micro-motions that gradually disengage the collapsed finger-trap. In contrast, RigidLoop Adjustable devices are designed with a one-way sliding-locking knot that wedges into the metal implant to resist disengagement. The tighter the knot is cinched, the better the performance. Failure of this mechanism may occur if the knot is left loose. They concluded that the "knot-based" design outperforms the "finger-trap" design for both cyclic displacement and strength.

Some investigated other parameters like tunnel length in porcine femur[33], elongation at lower[37] and higher loads[29 36]; number of cycles[31 37]; etc. Some studies considered the effect of re-tensioning and knot tying[36 37 31]. Two found it improved the biomechanical properties of the adjustable loop devices[37 31], whereas one did not improve them significantly[36]. All the porcine femur based biomechanical studies[29 33 37 30] reported their main limitation as porcine femur construct not being a true replication of in vivo mechanics, as the line of force in this model was in the line of tunnel. Also the results could potentially vary between the different femora due to differences in bone density.

The clinical studies in our review were either retrospective cohort or case series[35 41 32 42], two were prospective[39 38]. We did not find any RCTs or multi-centre trials. All clinical studies investigated anterior laxity of the knee at 6 moths to 2 years follow-up. Some researched tibial and femoral tunnel widening[41], only femoral tunnel widening[39 38], or the space in the femoral tunnel above the ACL graft[32]. In addition to hamstring autografts, Wise et al[42] also used tibialis anterior and tibialis posterior allografts, bone-tendon-bone auto- and allografts and hamstring allografts. Boyle et al[35] also compared graft revision rates and Wise at al looked at the re-rupture rates between adjustable and fixed loop devices. Both the studies found no significant difference. No clinical studies in our review found significant difference between patient groups with adjustable and fixed loop devices.

Most biomechanical studies reported that adjustable loops behaved less favourably (in terms of lengthening) than fixed loops when subjected to increasing load cyclical loading – in some studies adjustable loop devices lengthened more than 3mm, a cause for concern. They also tend to do poorly under lower loads, perhaps due to the “unlocking” of their adjustable mechanism. Re-tensioning and knot tying in most studies were found to improve the properties of adjustable loops; although researchers have noted the challenging nature of knot tying in live surgery. Various studies covered a realistic spectrum of loading forces that reconstructed ACL grafts might be expected to experience.

No clinical studies in our review found significant difference between patient groups with adjustable and fixed loop devices in terms of differences in stability, knee scores or graft failure between adjustable and fixed loop patients.

Although loop devices have been tested extensively in the laboratory they suffer the obvious limitations of being in-vitro studies. We can only hypothesize that this could be due to altered angles of ACL loading in vivo[31 36], influence of other confounding factors like graft healing[5 6 7 8], the role of additional supporting structures[48] and difference in bone mineral density of the human body[29 33 37 30]. Perhaps the ACL does not undergo high enough forces in early rehabilitation to cause elongation or the cycling of graft and fixing the tibial side with graft under tension mitigated the effects of elongation in the initial cycles[16 15 42].

Conclusions

There is a paucity of literature on adjustable loops, chiefly due to the fact that they have been introduced more recently. Although our review found that the adjustable loop devices elongate in the majority of laboratory based studies, on the basis of current evidence it is still unclear whether this translates into clinical instability.

We believe that this review will serve as a prompt to construct more robust and well-constructed randomised control trials to inform clear decisions regarding the safety and efficacy of adjustable loop devices.

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